

Exhibit 61

From: "OMahony, Kevin" <kevin.omahony@novartis.com>
To: xavier <xavier@huahaipharm.com>, tangyinhu <tangyinhu@huahaipharm.com>, "Quinn, Jannine" <jannine.quinn@novartis.com>, chenyingzhi@huahaipharm.com, "Breen, Sarah" <sarah.breen@novartis.com>, "Hu, Brad" <brad.hu@novartis.com>, "Zhu, Bin-1" <bin-1.zhu@novartis.com>, 徐覓 <xumi@huahaipharm.com>, 朱玲 <zhu ling@huahaipharm.com>, cai <cai@huahaipharm.com>, peng dong <dongpeng@huahaipharm.com>, xiongying <xiongying@huahaipharm.com>
Cc: minli <minli@huahaipharm.com>, jenson <jenson@huahaipharm.com>
Date: Thu, 07 Jun 2018 15:08:33 +0000
Attachments: Nitrosodimethylamine_es035025n.pdf (126.56 kB)

Dear All,

Please see below an update on activities at Novartis and some potential roots of synthesis provided by our R&D group.

Actions for confirmation of identity:

- Reference material for Nitrosodimethylamine has been received.
- Retention time analysis of the peak from the reference compared to the unknown in the GC and MRM using a triple quadrupole GC-MS will be performed to double check the identity. This is scheduled to be completed on Monday 11th June.
- If peak confirmed as Nitrosodimethylamine tentative quantitation of levels in three batches from which we can propose levels present in all batches tested so far.

Potential roots of formation:

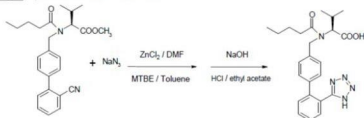
1. Leaching from rubber in the process equipment
2. Upon contact with tap water that has been pre-treated by chloramination (Cl₂ and NH₃), DMF might react to NDMA. See Table 1 in the attached paper. This pathway is reasonable only if at least some oxidant (such as hypochlorite in process water) would end up in process media that contain DMF and valsartan.

Please also make sure that any detected NDMA traces really originate from the test sample and not from water that is used in the analytical procedure. This may prove tricky in the ppb range.

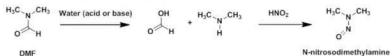
3. Two chemical steps in the ROS of Huahai (Step 3 and 4) use N,N-dimethylformamide (DMF) as a solvent. DMF is known to be subject to hydrolysis, releasing dimethylamine and formic acid, in particular at elevated temperature or in presence of acids or bases.

The critical step in the synthesis is the cyclization of the nitrile compound with sodium azide (NaN_3) to the tetrazole. This reaction is slow and must be kept at 0°C over several hours. Huahai uses ZnCl_2 in DMF to avoid the use of the traditional, but ecotoxic organotin reagent (tributyltin chloride).

Step 4 Synthesis of crude Valsartan



The reaction of Step 4 requires an excess of NaN_3 which has to be destroyed in the work-up. The common method to destroy excess azide is reaction with sodium nitrite and an acid to obtain HNO_2 which transforms azide into N_2 and N_2O . If dimethylamine is present, it would react with HNO_2 to form the N-nitroso compound:



A missing piece of evidence is the method by which Huahai actually destroys the excess azide of Step 4. Is this done by addition of sodium nitrite, and is this performed in presence of the valsartan product?

Best regards,

Kevin O'Mahony

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From: O'Mahony, Kevin
Sent: 07 June 2018 07:20
To: xavier; tangyinhua; Quinn, Jannine; chenyingzhi@huahaiapharm.com; Breen, Sarah; Hu, Brad; Zhu, Bin-1; 徐亮; 朱玲; cai; peng dong; xlongying
Cc: minli; jenson
Subject: RE: Valsartan

Dear Xavier,

I fully understand. But I still think it would be a good idea to have a quick call to discuss what we see so that you can have the most up to date information.

So maybe we can dial in for 15 minutes?

Best regards,

Kevin O'Mahony
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From: xavier [mailto:xavier@huahaiapharm.com]
Sent: 07 June 2018 09:37
To: O'Mahony, Kevin; tangyinhua; Quinn, Jannine; chenyingzhi@huahaiapharm.com; Breen, Sarah; Hu, Brad; Zhu, Bin-1; 徐亮; 朱玲; cai; peng dong; xlongying
Cc: minli; jenson
Subject: Re: Valsartan

Dear Kevin,

Thanks a lot for your invitation.

I have checked with Dr.U's team, actually it will take us some time to do study on the potential Nitrosodimethylamine impurity.

So may we suggest to postpone the TC to next week once we have more update and comments?

Certainly, if Novartis has anything new to update and share, we will appreciate it.

Best Regards

HUAHAI PHARM

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Email: xavier@huahaipharm.comLearn us more at www.huahaipharm.com**From:** O'Mahony, Kevin.**Date:** 2018-06-06 23:59**To:** [xavier](mailto:xavier@huahaipharm.com); [tangyinhua](mailto:tangyinhua@huahaipharm.com); [Quinn_Jannine](mailto:Quinn_Jannine@huahaipharm.com); [chenyingzhi](mailto:chenyingzhi@huahaipharm.com); [Breen_Sarah](mailto:Breen_Sarah@huahaipharm.com); [Hu_Brad](mailto:Hu_Brad@huahaipharm.com); [Zhu_Bin-1](mailto:Zhu_Bin-1@huahaipharm.com); 徐亮; 朱元; Cai peng dong; xiongying**Subject:** Valsartan

Dear All,

Please find details for a follow up call tomorrow to discuss the potential Nitrosodimethylamine impurity.

Best regards,

Kevin O'Mahony

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